REMARKS

Claims 3 and 4 are pending in the present application.

No new matter has been added by way of the present submission. For instance, claim 1 has been cancelled.

Further, the cancellation of claim 1 cannot raise any new issues which would require additional search and/or consideration on the part of the Examiner.

In the event that the present submission does not place the application into better form for appeal, entry thereof is respectfully requested as placing the application into better form for appeal.

In view of the following remarks, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

Issue under 35 U.S.C. § 102(b)

Claims 1, 3 and 4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hung, US 2002/0045260 (hereinafter referred to as Hung '260) in light of Whittle, 2000; Placenta (hereinafter referred to as Whittle). Applicants respectfully traverse this rejection.

The Present Invention as Recited in Claims 3 and 4

Independent claim 3 relates to a method for obtaining bone cells comprising culturing (a) bone stem cell(s) existing in human amniotic mesenchymal cell layer in a bone cell-differentiation medium.

Independent claim 4 is directed to a method for osteogenesis comprising transplanting bone stem cells existing in human amniotic mesenchymal cell layer into (a) bone defect(s).

Distinctions Between the Present Invention and the Cited Art

As seen above, each of claims 3 and 4 require bone stem cell(s) existing in human amniotic mesenchymal cell layer. However, **none of the cited references discloses or suggests that the mesenchymal cell layer contains bone stem cells**. This is an important distinction that cannot be ignored.

Applicants note that the Examiner alleges that "Hung et al. teach mesenchymal stem cells capable of differentiating into bone cells (see abstract)" (page 3, last paragraph of Final Office Action). However, Applicants respectfully submit that this is incorrect. Nowhere in the abstract of Hung '260 is there a teaching or suggestion of the existence of bone stem cells in the mesenchymal cell layer. Rather, the "abstract" of Hung '260 simply teaches:

> The invention discloses a novel method of isolating mesenchymal stem cells (MSCs), which is characterized by purifying pluripotent MSCs based on physical characters and biological properties and without the uses of antibodies. The present invention also relates to the application of the isolated MSCs to serve as tissue replacement or gene therapy for tissues damaged by age, trauma, and disease.

The Examiner also makes reference to paragraphs 26, 32 and 37 of Hung '260, however, Applicants submit that close inspection of these disclosures does not reveal the presently claimed subject matter. These paragraphs are replicated below:

> [0026] According to the method of the present invention, any cells mixture containing MSCs can be the source materials for isolation. The source can derive from, for example, mammals (including human species), animals (e.g. rabbit), or plants. Suitable MSCs sources include, but are not limited to, fractioned tissues, un-fractioned tissues, bloods, or body fluids. Preferably, the MSCs sources include bone marrow, embryonic yolk sac, placenta, umbilical cord, and fetal, adolescent and adult body fluids and tissues, wherein the bone marrow can be obtained from iliac crest, femora, tibiae, spine, rib, or other medullary spaces.

> [0032] The present invention also comprises the application of such isolated MSCs, more particularly, in the form of pharmaceutical composition comprising a pharmaceutically acceptable carrier, which can be used for therapeutic or diagnostic purpose. For example, human MSCs are useful in: (1) providing an integral model of cell differentiation and tissue development to specific mesenchymal lineages; (2) developing mesenchymal cell lineages and assaying for factors associated with their differentiation and development; (3) detecting and evaluating growth factors or inhibitory factors which modulate MSCs proliferation and differentiation into specific mesenchymal lineages; (4) expanding a large scale of homogeneous/heterogeneous cells or tissues in vitro that can be implanted back into body combined with/without carriers, scaffolds, or bioactive factors such as cytokines; (5) producing various mesenchymal tissues for transplantation; (6) regenerating mesenchymal tissues which have been damaged by age, trauma, congenital, or acquired disease; and (7) genetically modulating culture-expanded MSCs ex vivo or in vitro to treat patients with mesenchymal tissue damages.

> [0037] The marrow mesenchymal cells 14 days following the first passage were cultured in DMEM-LG supplemented with 10% FBS. The cell culture was also treated with one of the following formulas: (1) osteogenic differentiation medium: 50 μg/ml of ascorbate-2-phosphate (Sigma Co.), 10^{-8} M of dexamethasone (Sigma Co.), and 10 mM of .beta.-glycerophosphate (Sigma Co.); (2) adipogenic differentiation medium: 50 μg/ml of ascorbate-2-phosphate, 10^{-7} M of dexamethasone, and 50 μg/ml of indomethacin (Sigma Co.); (3) chondrogenic differentiation medium: 10 ng/ml TGF-β_1 in serum free aggregation condition. The medium was changed every 4 days and cells were used for histochemical or immunohistochemical analysis after the completion of differentiation by identified morphology.

Nowhere in the above paragraphs, and in fact nowhere within the disclosure of Hung '260 is there any teaching or suggestion of culturing of the mesenchymal stem cells in a bone cell-differentiation medium as required in claim 3. Whittle does not change this outcome. Similarly, neither Hung '260 nor Whittle teach or suggest to transplant the mesenchymal stem cells into a bone defect as required in claim 4. For a rejection to constitute "anticipation", all material elements of a claim must be found in the cited art reference. In re Marshall, 577 F.2d 301, 198 U.S.P.Q. 344 (CCPA 1978). Also, anticipation is not established if in reading a claim or something disclosed in a reference it is necessary to pick, choose and combine various

portions of the disclosure not directly related to each other by the teachings of the reference. In re Arkley, 455 F.2d 586,587-88, 172 U.S.P.Q. 524, 526 (CCPA 1972); see also ex parte Beuther, 71 U.S.P.Q.2d 1313, 1316 (Bd. Pat. App. & Inter. 2003) (unpublished). Lastly, a theory of inherency must be supported by facts and/or technical reasoning that reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy* 17 USPQ2d 1461 (BPAI 1990) (emphasis added). In order for prior art to anticipate a claimed compound on the ground it is inherently produced in a prior art process, the inherency must be certain. Glaxo, Inc. v. Novopharm Ltd., (EDNC 1993) 830 F. Supp 871, 29 USPQ2d 1126; Ex parte Cyba (POBA 1966) 155 USPQ 756; Ex parte McQueen (POBA 1958) 123 USPQ 37. The fact that a prior art article may inherently have the characteristics of the claimed product is not sufficient. Ex parte Skinner (BPAI 1986) 2 USPQ2d 1788. Inherency must be a necessary result and not merely a possible result. In re Oelrich (CCPA 1981) 666 F2d 578, 212 USPQ 323; Ex parte Keith et al. (POBA 1966) 154 USPQ 320.

Therefore, it is believed that claims 3 and 4 in the present application are not anticipated by the cited art. In view of the above, Applicants believe that the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Reg. No. 42,874, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: July 2, 2009

Respectfully submitted,

By _____

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